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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/786,505	02/25/2004	Richard W. Gross	15060-42	5478

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EXAMINER	
RAGHU, GANAPATHIRAM	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 03/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/786,505	GROSS ET AL.	
	Examiner	Art Unit	
	Ganapathirama Raghu	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-48* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-48 are pending in this application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 16-17, 34-35, 37, and 40-48, drawn to polynucleotide, expression vectors, host cells and the method of making polypeptides consisting of the following SEQ ID NOs: 3-10, 13, 16, 22, 29-30, 57, 59-62, 77 and 84, classified in class 435, subclass 69.1+.

II. Claims 10-14, 36 and 39 drawn to isolated polypeptide and fragments for phospholipase A2γ, wherein the polypeptide comprises an amino acid sequence selected from group consisting of the following SEQ ID NOs: 1, 2, 15, 18, 21 and 40-42, classified in class 435, subclass 183+.

III. Claim 15, drawn to an antibody that specifically binds to the isolated phospholipase A2γ polypeptide encoded by SEQ ID NO: 1, classified in class 530, subclass 387.1+.

IV. Claim 18, drawn to a method of administering a mouse $iPLA_2\gamma$ polypeptide as set forth in SEQ ID NO: 1 or 2 or variant thereof or administering the mouse a polynucleotide sequence encoding the said polypeptide wherein the repressor binding site comprises SEQ ID NO: 10, classified in class 514, subclass 44.

V. Claim 21, drawn to a method of preparing transgenic mouse, comprises breeding a transgenic founder mouse having SEQ ID NO: 1 stably integrated in its genome with WT B6CBAE1/J mouse, classified in class 800, subclass 21+.

VI. Claims 22-24, 26 and 38, drawn to a transgenic mouse, wherein the recombinant polynucleotide with any one of the SEQ ID NOs: 1-9 or conservative variants thereof, encoding the phospholipase A2γ polypeptide or the recombinant polynucleotide has the sequence as set forth in SEQ ID NO: 10, classified in class 800, subclass 8+.

VII. Claim 31, drawn to a mitochondrial targeting sequence classified in class 530, subclass 300+.

VIII. Claim 32, drawn to a mitochondrial import signal sequence and cleavage site classified in class 530, subclass 300+.

IX. Claim 33, drawn to a subcellular localization signal sequence into both peroxisomes and mitochondria classified in class 530, subclass 300+.

The inventions are distinct, each from the other because of the following reasons:

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

Inventions I-III, VI-IX are drawn to products and are patentably distinct from each other. The polynucleotide of group I, the polypeptide of group II, the antibody of group III, the transgenic mouse of group VI and the short peptides of groups VII-IX with different biological functions, each comprise of nucleic acids, amino acids, intact animals, that are chemically

unrelated, do not require each other for practice; have separate utilities. For example the use of group I polynucleotide in a hybridization reaction versus the group II polypeptide to catalyze a biochemical reaction, are subject to separate manufacture and sale. The groups have acquired a separate status in the art and separate fields of search.

Inventions IV, V are drawn to methods and are patentably distinct from each other. The method of administering a mouse in group IV either with a polypeptide or polynucleotide or the method of making a transgenic mouse by breeding, involve different steps and processes and are subject to separate manufacture and sale. The groups have acquired a separate status in the art and separate fields of search.

Inventions I and IV, V are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of group I can be used as a probe in hybridization reaction as opposed to its use in the method of group IV for administering a mouse with the polynucleotide or generating transgenic mouse expressing the polypeptide in group V.

Inventions II and IV are related as products and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide of group II can be used to catalyze an enzymatic

reaction as opposed to its use in the method of group IV for administering a mouse with the polypeptide.

Inventions II and method V are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, polypeptide of group II is neither used nor made in the method of group V that involves breeding a transgenic founder mouse. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions III, VII, VIII, IX and methods IV, V are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, antibody of group III, the short peptide signals of groups VII-IX are neither used nor made in the method of group IV and V that involves either administering a mouse with a polypeptide or polynucleotide or breeding a transgenic founder mouse. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Invention IV and product VI are unrelated to each other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, product of group VI that comprises a transgenic mouse and the method of administering a mouse with polypeptide or polynucleotide of group IV are neither used nor made

in making the product of group VI. They are subject to separate manufacture and sale. The groups have acquired separate status in the art and separate fields of search.

Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product of invention VI (a transgenic mouse) can be made with a vector using recombinant technology as opposed to breeding a founder mouse in group V, therefore the product of invention VI can be made by materially different process.

Examiner notes that there are serious flaws in claim language and claim dependency with respect to claims 18-20, 25, and 27-31 because of which they have not been included in any of the restricted groups. For example,

a) Claim 18 is a method that involves administering a polynucleotide is dependent on claim 30 that is directed to a product, a genetically engineered cell,

b) Claims 19 and 20 are directed to a product, a genetically engineered cell that is dependent on claim 18, drawn to a method that involves administering a polynucleotide,

c) Claim 25 is a product, a vector that is dependent on claim 24 another product, a transgenic mouse. These should have been independent claims,

d) Claims 27-29 are directed to a transgenic mouse but dependent from claims 6-8 respectively that are directed to another product-DNA. These claims should be independent claims or should have proper dependency,

e) Claim 30 is drawn to a product, a genetically engineered cell that is improperly dependent on claim 31 that is drawn to a peptide fragment. Furthermore, the peptide sequence recited in the claim contains an amino acid code Δ, not in accordance with scientific convention and unsearchable

Examiner made several attempts during Dec. of 2005 to bring this to the attention of the applicant to request properly dependent claims. However, there has been no response from the applicant. Examiner suggests canceling of claims not included in any of the groups or submission of a set of amended claims so that a proper restriction can be made.

A shortened statutory period for reply to this action is set to expire ONE MONTH or THIRTY DAYS, whichever is longer, from the mailing date of this letter.

Election of Sequence

Groups I and II contain claims directed to the following patentably distinct species of the claimed invention: the various sequences recited in the claims (Group I polynucleotide sequences with SEQ ID NOs: 3-10, 13, 16, 22, 29-30, 57, 59-62, 77 and 84 and Group II amino acid sequences with SEQ ID NOs: 1, 2, 15, 18, 21 and 40-42) have specific activities. Furthermore these sequences have different structure and function.

Applicant is required under 35 U.S.C. 121 and 372 to elect a single appropriate disclosed species i.e., a single SEQ ID NO: associated with the respective group for prosecution on the merits to which the claims are restricted. Note that this is a restriction requirement to sequence and NOT a species election.

MPEP 803.04 states: Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed

to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141et seq. It has been determined that 1(ONE) sequence constitutes a reasonable number for examination purposes under the present conditions. At present the huge number of submissions of claims directed to various sequences, such as nucleic acids or polypeptides, is so large that the election of sequence of this type is now deemed to be practically appropriate so as to not overwhelm the examination and search processes for such claims. Examination will be restricted to only the elected group and the elected amino acid /nucleotide sequence.

Hence, the above inventions have acquired separate status in the art and separate fields of search.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Rejoinder of restricted inventions

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. Thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim

will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652

Feb. 23, 2006.

RAMAKRISHNA N. RAO, PH.D.
PRIMARY EXAMINER